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REMARKS

Claims 5, 10, and 15 have been amended to specify that the claimed "mimicking" effect on skin of retinoic acid mimicks the effects of treatment with retinoic acid of acne, wrinkles, psoriasis, age spots and discoloration. Support for this amendment may be found in the Specification, page 1, lines 18-23.

Claim 16 has been amended to specify a booster combination of climbazole (B5) and alpha-ionone (B1). Support for this amendment may be found throughout the Specification, including the Tables on pages 23 and 37.

Independent claims 1, 6, and 11 have been amended to delete reference to dimethyl imidazolidinone and linoleamide DEA. These amendments have been made in the interest of progressing the present case to issue without delay, and are not believed to be necessary for patentability.

New Claim 17 has been added to depend from Claim 1 and claim an emollient. Support for this amendment is found in the Specification, page 34.

New Claim 18 has been added to depend from Claim 1 and claim the booster alpha-ionone. Support for this amendment is found throughout the Specification, and on page 23 for example.

Care has been taken not to introduce any new matter.

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The Present Invention

The present invention is directed to a new and unobvious combination of specified retinoids and specified retinoid boosters in a **dual compartment package, where the compartments are joined together**, intended to avoid chemical degradation of retinoids that would be caused by contact with the retinoid boosters. The specified retinoid boosters, despite boosting the effect of specified retinoids on the skin, tend to destabilize the specified retinoids in the composition. The claimed retinoid boosters are among a specific list that has been demonstrated to de-stabilize retinoid to a greater extent than the retinoids would be unstable in the absence of the boosters. Therefore, with respect to the specified retinoid boosters, there is a greater stability problem, as shown in the table on page 37 of the Specification. The retinoid/retinoid booster combinations are maintained in separate compartments of a package and the retinoid composition is kept out of contact with oxygen to promote its stability against chemical degradation and to avoid further instability that would be caused by contact with retinoid boosters.

Claim Rejections - 35 USC § 112

Claims 5, 10 and 15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While Applicants respectfully traverse this rejection, it is respectfully submitted that this rejection has been rendered moot by the claim amendments.

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Applicants respectfully submit that the claims are clear to the effect that a combination of a claimed retinoid (**excluding retinoic acid**) and specified boosters *mimick the effects of retinoic acid*. The effects of retinoic acid are described in detail throughout the Specification, **and are now specifically recited in the claims**. The unexpected result of the present invention is that compositions that do not contain retinoic acid behave **analogously to treatment with retinoic acid** (i.e. *mimick*), as if they did contain the most active form of retinoid, i.e., retinoic acid.

Claim Rejections - 35 USC § 103

Claims 1, 4-6, 9-11 and 14-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (USPN 5,536,740) in view of Soares et al. (USPN 5,914,116) and Liu et al. (USPN 5,976,555).

According to the Office Action, Granger et al disclose a skin conditioning composition comprising a compound selected from retinol or retinyl ester in combination with *dimethyl imidazolidinone*, and a method. The Office Action admits that Granger et al '740 does not disclose the first compartment for storing retinol or retinyl ester kept out of contact with oxygen, and the second compartment for storing *dimethyl imidazolidinone*, and the first and second compartments being joined together; and avoiding chemical degradation of retinol or retinyl ester in the first composition that would be caused by contact with dimethyl imidazolidinone in the second composition.

According to this and previous Office Action, Soares et al. (USPN 5,914,116) teaches a method for a skin treatment comprising a topical application regime and a

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respective product; The product includes a first composition containing at least one active (0.10% Vitamin A palmitate), and a second composition including a second active (0.30% fragrance, and 3.00% stearic acid); The first and second compositions are stored in respective separate containers which are joined together.

The *previous* Office Action admits that Soares et al. (USPN 5,914,116) does not teach that the first and/or second compartments keep the respective compositions out of contact with oxygen, neither does it teach that the two compartments are made of aluminum. However, Liu et al. is cited to supposedly remedy the deficiency for its teaching that retinal and retinyl esters quickly lose their activity and oxidize or isomerize.

Applicants traverse this new rejection and would like to point out that that the newly cited primary reference, Granger et al. '740, does not render the present invention obvious. Granger et al '740 is missing the crux of the present invention, i.e., all the elements admitted in the Office Action as missing. The secondary references do not remedy the deficiency of Granger et al any more than they previously rendered the invention obvious. In the interest of progressing this case to issue without delay, Applicants have removed reference to dimethyl imidazolidinone from independent Claims 1, 6, and 11.

As stated in the previous response, the independent claims 1, 6 and 11, as amended, relate to specific booster compounds that are shown to de-stabilize the claimed retinoids to a greater extent than the degree of instability in the absence of the boosters. See the table on page 37 of the Specification. For example, the results in the Table show that *alpha-ionone* (*B1 booster*) increases the rate of retinol loss by a

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factor of 1.3. Similarly, it can be seen that all the claimed boosters significantly increase the rate of retinol loss. Therefore, the **presence of the boosters necessitates separate compartments for the two compositions**, more so than the cited art. *These are unexpected results.*

Applicants respectfully submit that Liu et al. do not remedy the deficiency of Granger et al '740. Firstly, Liu et al. merely restate the problem. Liu et al. merely state an invitation to invent by restating that retinoids are unstable. Liu et al. do not address the problem to which the present invention is addressed, i.e., alleviating the additional instability contributed by boosters. (At most, Liu et al. provide a different solution – i.e. formulating in an emulsion with a specifically defined stabilizer system, but all in one composition.) Secondly, the combination of Granger et al '740, Soares et al. and Liu et al. does not arrive at the subject matter of the present invention as claimed in Claims 1, 6 and 11, as amended. Although Liu et al. describe a container for storing the composition so that it is out of contact with oxygen, the container is described in combination with a retinoid composition with an emulsifier system and a co-emulsifier alone and does not protect the retinoid from degradation due to contact with retinoid boosters.

Accordingly, Liu et al and of Soares et al. do not remedy the deficiencies of Granger et al. In fact, none of the references cited in the Office Action teach or suggest the need or the solution for stabilizing retinoid compositions in the presence of retinoid enhancing actives. Therefore, although dual purpose single formulation cosmetic products have been developed in the cited art, only in hindsight, with the benefit of the disclosure of the present invention, is the need for stable cosmetic compositions that attenuate the existing problems of retinoid stability in the presence of boosters met.

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Claims 3, 8 and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (USPN 5,536,740) in view of Soares et al. (USPN 5,914,116) and Liu et al. (USPN 5,976,555) and Remington's Pharmaceutical Sciences (Remington). According to the one or more of the Office Actions, Remington in a subsection entitled "pharmaceutical containers" in the chapter on stability of pharmaceutical products teaches that aluminum containers are widely used in the pharmaceutical products.

As discussed above, Granger et al is an insufficient primary reference and the secondary references do not remedy its deficiencies. Moreover, the independent claims on which claims 3, 8, and 13 depend have been amended to exclude the booster disclosed in Granger et al '740. A further combination with Remington does not arrive at the subject matter of the dependent claims 3, 8, and 13.

Furthermore, there is no motivation to combine **Granger et al ('740)** with Remington, Soares et al. and Liu et al. because Remington deals with high temperature storage. High temperature storage is not relevant to the present invention. Again, even if combined, Applicants respectfully submit that, since the independent claims are in condition for allowance, those claims that depend from them are also in condition for allowance.

Claims 1-2, 4-7, 9-12 and 14-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (USPN 5,716,627) in view of Soares et al. (USPN 5,914,116) and Liu et al. (USPN 5,976,555).

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According to the Office Action, Granger et al disclose a skin conditioning composition comprising a) retinol or retinyl ester, b) azole, c) a fatty acid amide such as linoleoyl-DEA. The Office Action admits that Granger et al '627 does not disclose

the first compartment for storing retinol or retinyl ester kept out of contact with oxygen, and the second compartment for storing dimethyl imidazolidinone, and the first and second compartments being joined together; and avoiding chemical degradation of retinol or retinyl ester in the first composition that would be caused by contact with dimethyl imidazolidinone in the second composition.

Applicants traverse this rejection and would like to point out that that the newly cited primary reference, Granger et al. '627, does not render the present invention obvious. Granger et al '627 is missing the crux of the present invention, i.e., all the elements admitted in the Office Action as missing. The secondary references do not remedy the deficiency of Granger et al any more than they previously rendered the invention obvious. In the interest of progressing this case to issue without delay, and without believing that the amendment is necessary for patentability, Applicants have removed reference to linoleamide DEA from independent Claims 1, 6, and 11.

As stated in the previous response, the independent claims 1, 6 and 11, as amended, relate to specific booster compounds that are shown to de-stabilize the claimed retinoids to a greater extent than the degree of instability in the absence of the boosters. See the table on page 37 of the Specification. For example, the results in the Table show that *alpha-ionone* increases the rate of retinol loss by a factor of 1.3. Similarly, it can be seen that all the claimed boosters significantly increase the rate of retinol loss. Therefore, the **presence of the boosters necessitates separate**

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Accordingly, Liu et al and Soares et al do not remedy the deficiencies of **Granger et al '627**. In fact, none of the references cited in the Office Action teach or suggest the need or the solution for stabilizing retinoid compositions in the presence of retinoid enhancing actives. Therefore, although dual purpose single formulation cosmetic products have been developed in the cited art, only in hindsight, with the benefit of the disclosure of the present invention, is the need for stable cosmetic compositions that attenuate the existing problems of retinoid stability in the presence of boosters met.

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As discussed above, Granger et al '627 is an insufficient primary reference and the secondary references do not remedy its deficiencies. Moreover, the independent claims on which claims 3, 8, and 13 depend have been amended to exclude the booster disclosed in Granger et al '627. A further combination with Remington does not arrive at the subject matter of the dependent claims 3, 8, and 13.

Even if there were motivation to combine **Granger et al '627 with Remington** with Soares et al. and Liu et al., the art combination with Remington only potentially relates to the dependent claims 3, 8 and 13 of the present invention, i.e., those specifying that the preferred oxygen impermeable material is aluminum. Furthermore, there is no motivation to combine Remington with Soares et al. and Liu et al. because Remington deals with high temperature storage. High temperature storage is not relevant to the present invention. Again, even if combined, Applicants respectfully submit that, since the independent claims are in condition for allowance, those claims that depend from them are also in condition for allowance.

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Claim Rejections –Double Patenting

Applicants traverse these rejections.

Applicants respectfully point out that the double patenting rejections under the judicially created doctrine of obviousness-type double patenting is improper because it requires reference to Remington, which is not commonly owned with this application.

Additionally, as discussed above, Applicants believe that these rejections have been rendered moot by the claim amendments.

Furthermore, the rejection of claims 1-16 is moot because Application 10/004,508 (Attorney Docket No. J6675(C)) has been abandoned.

Application Serial No. 10/008,067 is attorney docket no. J6667(C) , and Applicants would consider supplying a terminal disclaimer, except that Applicants believe the combination with Remingtons' which is not commonly owned renders the rejection defective.

To the extent any double patenting rejections may remain , Applicants would be willing to supply a terminal disclaimer upon indication of allowability of the present claims.

Applicants respectfully submit that, since the independent claims are in condition for allowance, those claims that depend from them are also in condition for allowance.

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In view of the foregoing amendments and comments, Applicants request the Examiner to reconsider the rejection and now allow the claims.

Respectfully submitted,



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